

II. REMARKS

The undersigned gratefully acknowledges the courtesies extended by Examiner Fubara during the interview conducted on December 14, 2004.

A. Status of the Claims

Claims 1, 4, 6, 8-20, 24-33, and 35-39 are currently pending in the present application. Claim 3 has been cancelled without prejudice. Claims 1, 6, 8-9, 12, 15, 18, 24, 27, 31, 33 and 35 have been amended without prejudice. Support for the amendments can be found throughout the original specification as filed. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

B. Statement of Substance of Interview

During the Interview of December 14, 2004, all of the pending claims were discussed. Applicants proposed to limit the claims to "...an active agent consisting of metformin..." in order to overcome the Scott reference. The Examiner stated that this amendment appears to overcome the Scott reference.

Applicants also proposed to limit the method claims to "swallowing an intact dosage form" as the Barry reference, which describes dispersible or effervescent dosage forms, does not teach or suggest this limitation. The Examiner stated that this amendment would be considered.

Also, with respect to the Barry reference, Applicants stated that one skilled in the art would not be motivated to choose metformin from the large list of active agents described therein. It was further stated that Barry cannot inherently disclose the present "AUC" limitation as they did not exemplify a metformin formulation or indicate that they ever made a metformin formulation. It was also discussed that in order to formulate a metformin formulation in accordance with Barry, conditions, ingredients and parameters would have to be optimized as Barry does not specifically teach how to formulate metformin utilizing their described technology. Accordingly, it was discussed that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

(reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).

C. Rejections over Scott (U.S. 3,621,097)

In the Office Action, claims 1, 3, 4, 6, 8-20 and 24-32 were “rejected under 35 U.S.C. §102(b) as being as being anticipated by Scott (US 3,621,097).”

In response, the pending claims have been amended without prejudice to recite “...an active agent consisting of metformin...”

It is respectfully submitted that the Scott reference is directed, in part, to a pharmaceutical composition comprising a dimethyl biguanide and an ataractic. As discussed during the interview, the Scott reference does not teach or suggest the claimed sustained release formulation of metformin without an ataractic. Therefore, as the claims now recite “consisting of metformin”, the Scott reference cannot anticipate the presently claimed sustained release formulation.

D. Rejections over Barry et al. (U.S. 5,055,306)

Claims 33 and 35-39

In the Office Action, method claims 33 and 35-39 were “rejected under 35 U.S.C. §103(a) as being as being unpatentable over Barry et al. (US 5,055,306).”

In response, as discussed during the interview, independent claims 33 and 35 have been amended to recite “...swallowing an intact dosage form...”

It is respectfully submitted that the Barry reference is directed to effervescent or water dispersible dosage forms which are administered by disintegrating the dosage form in an aqueous liquid prior to administration (see column 5, lines 43-55 of Barry) or by sucking and swallowing material released from the tablet (see column 10, lines 46-54 of Barry). As discussed during the interview, the Barry reference does not teach or suggest “...swallowing an intact dosage form...”

Therefore, the Examiner is requested to remove the rejection of claims 33 and 35-39 over the Barry reference.

Claims 1, 3, 4, 6, 8-20 and 24-32

In the Office Action, claims 1, 3, 4, 6, 8-20 and 24-32, were “rejected under 35 U.S.C. §102(b) as being anticipated by Barry et al. (US 5,055,306).

The Examiner stated that “...the function of the instant metformin formulation is inherent in the metformin formulation [of Barry].”

In response, as-discussed during the interview, in order to formulate a metformin formulation in accordance with the Barry reference, conditions, ingredients and parameters would have to be optimized as Barry does not specifically teach how to formulate metformin utilizing their described technology. Accordingly, it was discussed that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich.

Further, it is respectfully submitted that the Barry reference states that the formulations described therein can be used with a large genus of possible active agents. This genus is listed in the Barry reference at column 7, lines 8-46. This exhaustive genus includes a multitude of compounds and the recitation of metformin (line 36) is merely a single species of the large genus described in the Barry reference.

It is respectfully submitted that one skilled in the art would not be motivated to select the particular claimed species (i.e. metformin) from the large genus disclosed at column 7 of the Barry reference. In support of this position, it is respectfully submitted that with respect to Barry, (i) the size of the genus is not sufficiently small as to render each member of the genus inherently disclosed, (ii) the reference does not expressly teach a particular reason to select the claimed species; and (iii) there is no teaching of structural similarity in the reference. A discussion of these points follows:

(i) The size of the genus is not sufficiently small as to render each member of the genus inherently disclosed

The fact that a claimed species is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Some motivation to select the claimed species or subgenus must be taught by the prior art. See e.g., *In re Deuel*, 51 F.3d at 1558-59, 34 USPQ2d at 1215.

It is respectfully submitted that the size of the possible active agents which can be used in accordance with the Barry reference is sufficiently large as not to render obvious each and every individual species (e.g. metformin) which falls within their broad genus.

(ii) The reference does not expressly teach a particular reason to select the claimed species

If a prior art reference expressly teaches a particular reason to select the claimed species, the Examiner should point out the express disclosure which would have motivated one of ordinary skill in the art to select the claimed species. See MPEP 8th Edition, 1st revision 2144.08 II (A)(4)(B). It is respectfully submitted that the only recitation of metformin in the Barry reference is embedded within a large genus. Accordingly, the Barry reference does not expressly teach a particular reason to select metformin from the plethora of other possible species in the genus of the reference.

(iii) There is no teaching of structural similarity in the reference

If a preferred species is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species from the genus. See, e.g., *In re Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. It is noted that the preferred active

agents exemplified in the Barry reference are ibuprofen, nifedipine, naproxen and mefenamic acid in Examples 1 - 8.

It is respectfully submitted that none of these agents are similar in structure to metformin (i.e., dimethyl biguanide). Accordingly, as the Barry reference does not teach any preferred species which have structural similarity to metformin, there is no motivation therein to one skilled in the art to select metformin from the large genus.

Further, any teaching or suggestion in the reference of a preferred species that is significantly different in structure from the claimed species weigh against selecting the later selected species. Baird, 16 F.3d 382-83, 29 USPQ2d 1552 (Fed. Cir. 1994). Accordingly, the examples of the Barry reference directed to compounds that are not structurally similar to metformin is further evidence that one skilled in the art would not be motivated to select metformin from the genus described therein.

In view of the above remarks, the Examiner is requested to remove the rejection of claims 1, 3, 4, 6, 8-20 and 24-32 over the Barry reference.

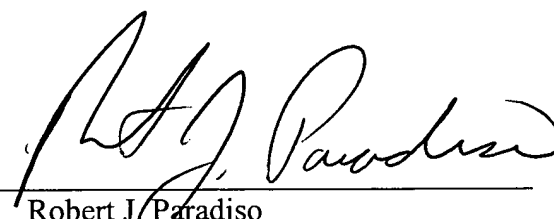
III. Conclusion

It is respectfully submitted that in view of the actions taken and arguments presented, that this case is now in condition for allowance. An early and favorable action on the merits is earnestly solicited.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 
Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940